REMARKS

Applicants submit these remarks with a Request for Continued Examination in response to the Office Action dated June 9, 2008 (hereinafter "Office Action"). Applicants submit the present response less than two months from the date of the Final Rejection. Therefore Applicants believe that this response is timely filed. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fees to Deposit Account No. 23-2415, referencing Docket No. 31747-705.201.

At the outset, the undersigned Applicants' representative wishes to thank Examiners Teller and Tate for the courteous telephonic interview conducted with Applicants' representatives on July 28, 2008. During the interview, the Examiners provided helpful comments and suggestions. The amendments and remarks submitted herein are based on the Examiners' comments and suggestions and are believed to place the application in condition for allowance. The substance of the interview is further summarized below.

Claims 2 and 6-12 and new Claim 38 are pending. Claims 2 and 38 are independent claims.

The Examiner has rejected claims 2 and 6-12.

Claim 2 is currently amended and new Claim 38 is added. It is believed that no new subject matter is introduced by the amendments.

By the above amendments, Claim 2 has been revised to recite a "selective antagonist to denatured collagen type-IV wherein said antagonist is a peptide" instead of a "denatured collagen type-IV selective peptide antagonist." This amendment is offered to provide more clarity as suggested by the Examiners during the interview. Applicants also amended dependent Claims 6-9, consistent with the amendment to Claim 2. Applicants believe that these amendments should not change the scope of the claims as previously presented.

Also, consistent with the discussions during the interview, Applicants have added new Claim 38. Support for new Claim 38 is provided throughout the specification as originally filed. See for example paragraphs [0059], [0061] and [0068].

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such action is earnestly solicited.

Claim Rejection – 35 U.S.C. § 102/103

Claims 2, and 6-12 stand rejected, under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over, Brooks et al. (U.S. Patent No. 7,122,635), hereinafter "the '635 patent." The rejection under 35 U.S.C. § 102/103 is respectfully traversed for at least the following reasons.

During the interview, the rejection under 35 U.S.C. § 102/103 was discussed. Applicants' representatives presented explanations distinguishing the present claims from the disclosure of the '635 patent. In particular, Applicants' representatives indicated that the '635 patent provides no disclosure of any amino acid sequence for a peptide antagonist to denatured collagen type-IV, much less a peptide comprising SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. The Examiners agreed that the '635 patent does not disclose the sequences recited in the present claims. The Examiners asked that the claims be revised to more clearly delineate the peptide nature of the presently claimed antagonists. The above amendments are offered in response to the concerns expressed by the Examiners during the interview and are believed to provide the clarifications requested by the Examiners.

The Examiners also requested additional clarification of the record that Applicants do not intend the claims in this application to cover antibodies. In this regard, it is submitted that the present claims are directed to peptides and polypeptides and not to antibodies. That the present claims are directed to peptides and polypeptides and not to antibodies is supported by the plain language of the claims and the disclosure in the Specification. See for example, paragraphs [0013] and [0014]. Illustration of peptides according to the present claims is provided in the Examples and the appended sequence listing which describes exemplary peptide sequences.

Returning to the 102 rejection, a reference is only good for what it clearly and definitely discloses. As noted by the Federal Circuit, anticipation under 35 U.S.C. § 102 occurs only "when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference." *Crown Operations International, Ltd. v. Solutia, Inc.*, 289 F.3d 1367 (Fed. Cir. 2002). "A single prior art reference anticipates a patent claim if it expressly or inherently

describes each and every limitation set forth in the patent claim." *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002). Moreover, the "single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116 (Fed. Cir. 2002). *See also In re Spada*, 911 F.2d. 705, 708 (Fed. Cir. 1990) (stating that "the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."); *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

Nowhere in the '635 patent is there described a selective antagonist to denatured collagen type-IV, wherein the antagonist is a peptide comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. The Official Action appears to allege that the '635 patent anticipates the present claims based on inherency.

According to the Office Action:

> "[i]t is acknowledged that the '635 patent does not disclose instant SEQ ID NO: 1, but given that the '625 patent discloses the same activity of antagonists that bind to the denatured collagen type-IV antagonist and given that an antagonist also can be a polypeptide or peptide with specificity for denatured collagen, but not for a native form of the collagen, it would be inherent that the activity should correlate to the structure of the denatured collagen type IV antagonist."

6/09/08 Office Action, pp. 3-4.

It is respectfully submitted that the Official Action fails to meet the burden of proof required by the Patent Office for a rejection based on inherency as set forth in MPEP § 2112.

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by

> persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)
>
> (MPEP 2112. IV.)
>
> Furthermore:
>
> In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).
>
> (MPEP 2112. IV.)

The "missing descriptive matter" at issue herein is at least the amino acid sequence of the peptides of the present invention. This descriptive matter is not "necessarily present in the thing described in the reference." Nowhere in the 06/09/08 Office Action is there provided reasoning which shows that the sequence of the peptide antagonists of the present invention "necessarily flow" from the teachings of the Brooks '635 patent.

The inherency argument is apparently based on the assumption in the Office Action that there is only one peptide antagonist having a single structure that correlates with the desired activity. It would appear that the Office Action equates the property of preferential binding to denatured collagen type-IV with the molecular structure of the antagonist. However, as discussed during the interview, this is not true. As discussed with the Examiners during the interview, antagonists having different structures may have similar binding properties to denatured collagen type-IV.

The Official Action appears to assert that the present antagonists are species that are anticipated by a genus disclosed in the '635 patent. However, the Office Action does not meet the requirements set forth in MPEP 2131.02 for "Genus-Species Situations." As set forth therein:

> When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be

> found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

The Office Action offers no evidence or reasoning to show that one of ordinary skill in the art is able to "at once envisage" the specific compound comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L within a generic chemical formula, assertedly disclosed in the '635 patent. The '635 patent discloses no structural formula for peptides that are antagonists to denatured collagen type-IV, much less a formula that would inherently disclose a peptide comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L.

Accordingly the rejection under section 102 should be withdrawn and such favorable action is respectfully requested.

Regarding the 103 rejection based on the '635 patent, Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness against the present claims. The Office Action does not appear to apply the proper standard by rejecting the claimed species as obvious over the genus disclosed in the '635 patent.

A fair reading of the '635 patent would indicate that while the '635 patent discloses a broad genus of peptides as potential antagonists to denatured collagen type-IV, the '635 patent does not suggest, much less disclose the claimed species which requires a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. That is the '635 patent mentions peptides and polypeptides as possible antagonists to denatured collagen type-IV, but the '635 patent does not at all provide structures for such peptide antagonists, much less a structure comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. In this regard, the MPEP provides that:

> The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed

compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

MPEP 2144.08 II.

Applicants respectfully submit that based at least on the fact that the '635 Patent does not disclose an antagonist comprising SEQ ID NO:1, the particular core sequence of the peptides as claimed in the present application would not have been obvious to one of skill in the art. In other words, an obviousness rejection based solely on the generic disclosure in the '635 patent that antagonists to collagen type IV may be in the form of a peptide or polypeptide and nothing more does not meet the requirements for establishing a prima facie case of obviousness against the present claims which require a peptide having a core sequence comprising SEQ ID NO:1.

Accordingly, the rejection under section 103 should be withdrawn and such favorable action is respectfully requested.

CONCLUSION

Applicants submit the above amendments and remarks with a Request for Continued Examination in response to the Office Action dated June 9, 2008. Applicants believe that for the reasons set forth above, the application is now in condition for allowance and such favorable action is earnestly solicited. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 23-2415 and please credit any excess fees to such deposit account.

Respectfully submitted,

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Dated: July 30, 2008

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